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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/893,005

06/28/2001

Hakuo Ikegami

IKEGAMI=2

6398

7590

04/20/2005

BROWDY AND NEIMARK, P.L.L.C.  
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EXAMINER

HELMER, GEORGIA L

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/893,005	<b>Applicant(s)</b> IKEGAMI ET AL.	
	<b>Examiner</b> Georgia L. Helmer	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 11-16, 18-21 and 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-16, 18-21 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

1. The Office acknowledges receipt of Applicant's Response of 28 January 2005, and of the certified translation of Applicant's foreign priority document.
2. Applicant has cancelled claims 1-10, 17, and 22-31, and amended claims 11, 20 and 21. Claims 11-16, 18-21 and 32 are pending, and are examined in the instant action.
3. This action is made FINAL necessitated by Applicant's amendment.
4. All rejections not addressed below have been withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112 second***

6. Claims 11-16, 18-19 and 32 remain rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention, for reasons of record.
  - line 1, "grown-up" is indefinite and ambiguous. A "grown-up" plant can be a plant at any stage from germinating seed to seed-set and senescence.  
Is this a flowering plant? Or a plant having seed?

Applicant traverses saying primarily (Response, p. 6) that Examiner has mistakenly associated the definition of the verb with that of the adjective, and that the dictionary definitions citations given are consistent with exemplary descriptions in the

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specification. Applicant states that Webster's defined "grown-up" as "adult". Applicant's traversal is unpersuasive. The metes and bounds of "grown-up" are not apparent.

Different people skilled in the art would define this term differently, encompassing different time periods. Further, while our society may define a person over 18 years old as an adult, it is unclear when adult would occur for a plant.

***Claim Rejections - 35 USC § 102***

7. Claims 11-16, 18-20 and 32 are rejected under 35 USC 102 (b) as being anticipated by Goodman, et al (US #4, 956, 282, issued September 11, 1990), for reasons of record.

Applicant traverses primarily that Goodman does not recite the "grown-up transgenic plant" in the sense of the present invention, whereas Goodman does state that call were obtained and their rooting promoted (Response, p. 10), that the disclosure of Goodman (column 5, lines 40-60) the cited paragraph using the words "may be" is just Goodman's hope or speculation and certainly not a disclosure, nor an enabling disclosure, that Goodman has not completed his invention with respect to "grown-up transgenic plant", and that Applicant's believe that the "grown-up transgenic plant" in which mammalian peptides exist in an advanced stage is part of Goodman's invention which has not been achieved (Response, p. 11). Applicant further traverses that the instant invention has advantage that would not have been expected from the disclosure of Goodman (Response, p. 12) and that the amended claims are drawn to a plant edible for mammals and humans, that a "tobacco plant" is considered in general not to be

edible for mammals and human, and that the transgenic plants of the claimed invention is thereby distinguished from Goodman (Response, p. 11).

Applicant's traversal is unpersuasive, for reasons of record, as repeated in part below. Applicant's claims (claim 11, lines 11-13) and all claims dependent thereon, are drawn to a transgenic plant comprising "a cytokine in an amount of 0.1 ng to one milligram per one kilogram by fresh weight of the grown up transgenic plant".

Applicant's method steps are identical to those of Goodman, as discussed above.

Applicant's starting materials are identical to Goodman's. Applicant did not specifically point to any evidence as to why Goodman is not enabling. Therefore, the percentage yield would have been an inherent property of the DNA construct used. If Applicant's percentage yields are different from that of Goodman, then the element(s) or step(s) resulting in such difference must be set forth in the claims to distinguish Applicant's invention to the prior art.

The scope of Goodman includes all plants other than seeds, which would encompass both "grown-up" plants and those which are not. Furthermore, while tobacco is one working example, Goodman specifically teaches edible plants, as previously indicated.

Accordingly Goodman anticipates the claimed invention.

***Claim Rejections - 35 USC § 103***

8. Claims 11-16, 18-21 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman, as discussed above for claims 11-16, 18-20 and 32, in

view of Goddign et. al. (Inhibition of trehalose activity enhances trehalose accumulation in transgenic plants, 1997, Plant Physiology Vol 113, pages 181-190).

The teachings of Goodman are discussed above. Goodman does not teach further supplementation with trehalose. The addition of sugars to food is notoriously well known. The supplementation of food with trehalose, a sugar, is a design choice well within the means of one of ordinary skill without any surprising or unexpected results.

Applicant traverses primarily (Response, p. 13) that since the certified English translation of the Japanese priority document filed 30 June 2000 has been provided by Applicant, the Vogel, 2001 reference is not available as prior art. Applicant's traversal is unpersuasive. Goddign et. al. (Inhibition of trehalose activity enhances trehalose accumulation in transgenic plants, 1997, Plant Physiology vol 113, pages 181-190) teaches the presence of trehalose in plants.

Accordingly, the claimed invention is prima facie obvious in view of the prior art.

#### **REMARKS**

9. No claims are allowed.
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

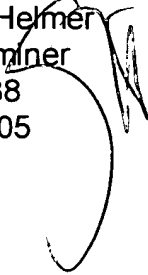
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

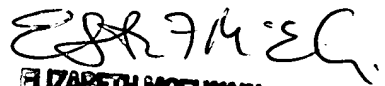
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer  
Patent Examiner  
Art Unit 1638  
April 18, 2005



  
ELIZABETH MCELWAIN  
PRIMARY EXAMINER